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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/379,308 08/23/99 DIAZ

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EXAMINER

HM22/0920

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ART UNIT

PAPER NUMBER

1654

DATE MAILED:

09/20/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 2.8 - 3.7 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 2.8 - 3.7 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Pursuant to preliminary amendment, claims 1-27 have been cancelled, and claims 28-37 added. Claims 28-37 are pending.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of treating various disorders, such as treatment of any and all unspecified "dermatological conditions", and more specifically alopecia, psoriasis, viral infections, acne and warts. In addition, the claims encompass treatment of cancer, cardiovascular disorders, diabetes, and ophthalmological disorders. However, the specification fails to provide any evidence that any of the compounds to which the method claims are drawn will exhibit any particular activity in any given assay. Applicants are merely speculating that one or more of the compounds will interact in some way with one or more receptors or cell types, and that this interaction will translate into a beneficial therapy. However, as it happens, one cannot reasonably draw conclusions about a

pharmacological activity merely be viewing a structure. Extensive experimentation is required even when a deliberate, rational approach to drug discovery is undertaken. But when compounds are selected at random, without evidence of biological activity of any kind, the probability of an effective therapy for any disorder becomes vanishingly small. Accordingly, at the very least, undue experimentation would be required of the skilled pharmacologist to discover which compounds, if any, can be used for any of the treatment methods to which the claims are drawn.

*

Claims 28-37 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

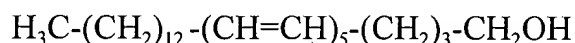
Claim 28 recites the following:

"A method...comprising administering...a compounds..."

There is an inconsistency as to whether a single compound is administered, or several compounds. In addition, "salts" and "optical isomers" (last line) should be in the singular if the claim is drawn to administration of a compound. (Applicants may of course add a claim drawn to administration of mixtures of compounds, if there is descriptive support in the specification).

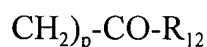
In claim 28, the term "geometrical isomer" renders the claim indefinite. This could be interpreted to mean that one can take any carbon atom at any position, and move it to any

other position. Thus, for example, stilbene could be viewed as a "geometrical isomer" of vinylbiphenyl; a peptide having the sequence RSDTPLK could be viewed as a "geometrical isomer" of the peptide RTSKLDP; and cholesterol, which has the formula $C_{27}H_{46}O$, could be viewed as a "geometrical isomer" of the following:



If, on the other hand, by "geometrical isomer", applicants intend only "cis/trans" isomers that result from substituents on a cycloalkyl ring, such isomers would be encompassed by the term "stereoisomers". It is suggested that the term "geometrical isomers" be eliminated from claim 28.

In claim 28, one of the possibilities recited for R1 is the following:



However, there is a missing left parenthesis; preferably also a dash ("-") should be present to indicate the site of bonding.

Claim 32 recites the following:

"A method...comprising administering...a compounds..."

There is an inconsistency as to whether a single compound is administered, or several compounds.

Each of claims 31-33 is drawn to a method of treating a given disorder by administering "a compound of claim 28". However, claim 28 is drawn to a method of treating a

dermatological condition, rather than to a compound *per se*. Accordingly, the claim dependence is not proper.

In claim 34, the term "differentiation of proliferation" lacks antecedent basis in claim 28.

In claim 35, the term "keratinization disorder" lacks antecedent basis in claim 28.

Claim 37 is dependent on a cancelled claim (claim 1).


*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
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